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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,788	KATO ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *11,13-17 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-10, 12 and 18 in the reply filed on November 5, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the claims 11, 13-17and 19 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Objections

2. Claims 12 and 18 are objected to because of the following informalities: Claims 12 and 18 are objected because they depend from the non-elected and withdrawn claims 11 and 17. Appropriate correction is required.

Claim Rejections - 35 USC § 101

Claims 12 and 18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10, 12 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims 1-10 are indefinite and vague overall because there is no clear nexus between the steps. Specifically it is unclear how the presence of the "cap" is involved in the synthesis reaction such that a conjugate is prepared. Additionally, the specification does not provide a limiting definition of the term "conjugate", how the claimed "conjugate" is achieved, or what portion of the mRNA/cDNA heteroduplex is considered the conjugate.. A clear interpretation of Applicant's intent cannot be ascertained.

(b) Claims 12 and 18 provides for the method of selecting a cDNA clone, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion (see *ex parte Erlich*, 3 UsPQ2d1011, p.1011 (Bd. Pat, Applicant. Int.1986). Clarification is required as to Applicant's intent.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note* Given the ambiguity of the claims, the preceding rejections are based on the examiner broadest, reasonable interpretation of the claims. Claim 1, 3-8, 10, 12 and 18, are rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al (US 5962271, October 1999). Regarding claim 1, Chenchik et al teach a method for synthesizing cDNA possessing a consecutive sequence starting with a nucleotide adjacent to a cap structure of mRNA, which method comprises the steps of: (i) annealing a double-stranded DNA primer and an RNA mixture containing mRNA possessing a cap structure, (ii) preparing a conjugate of an mRNA/cDNA heteroduplex and a double-stranded DNA primer by synthesizing the first-strand cDNA primed with the double-stranded DNA primer using reverse transcriptase, and (iii) circularizing the conjugate of the mRNA/cDNA heteroduplex and the double-stranded DNA primer by joining the 3' and 5' ends of the DNA strand containing cDNA using ligase (see figure 4-1 and 4-2, col. 3-5, 7-9 and Examples).

Regarding claim 3, Chenchik et al teach the method of claim 1, wherein mRNA possessing a cap structure is synthesized by in vitro transcription (col. 5, lines 11-53, and claim 1).

Regarding claim 4, Chenchik et al teach the method of claim 1, wherein the primer sequence of the double-stranded DNA primer contains a sequence complementary to a partial sequence of mRNA possessing a cap structure (see col. 7, line 52 to col. 8, line 43).

Regarding claim 5, Chenchik et al teach the method of claim 1, wherein the primer sequence of the double-stranded DNA primer contains an oligo dT complementary to a poly(A) sequence of mRNA possessing a cap structure (col. 7, lines 50-56).

Regarding claim 6, Chenchik et al teach the method of claim 1, wherein the ligase is T4 RNA ligase (col. 14, line 62 to col. 15, line 1).

Regarding claim 7, Chenchik et al teach the method of claim 1, which comprises the following step between the step (ii) and the step (iii): (ii') generating a 5'-protruding end or a blunt end at the terminal of the double-stranded DNA primer by cutting the conjugate of the mRNA/cDNA heteroduplex and the double-stranded DNA primer using a restriction enzyme (col. 11, Example 2).

Regarding claim 8, Chenchik et al teach the method of claim 1, which further comprises the following step: (iv) synthesizing the second-strand cDNA by replacing an RNA strand with a DNA strand in the conjugate of the mRNA/cDNA heteroduplex and the double-stranded DNA primer (col. 8, line 61 to col. 9, line 13).

Regarding claim 10, Chenchik et al teach the method of claim 8, which further comprises the following step: (v) incorporating the double-stranded cDNA composed of the first-strand cDNA and the second-strand cDNA into a vector DNA (Figure 4 and col. 14, line 62 to col. 15, line 2).

Regarding claim 12, and 18 A method for selecting a cDNA clone possessing a consecutive sequence starting with a nucleotide adjacent to a cap structure of mRNA, wherein a cDNA clone possessing a 5'-end nucleotide of (dT)ndG (n=0-5) is selected as an objective clone (col. 3, line 50 to col. 4, line 50). Therefore, Chenchik et al meet the limitations of the claims recited above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al as previously applied above in view of Chenchik et al (6,352,829, March 2002) {Chenchik '829, herein}. Regarding claim 2, Chenchik et al teach the method of

claim 1, wherein mRNA possessing a cap structure is in a tissue, e.g., biopsy tissue or tissue at different developmental stages, or a cell or pathogenic microorganism and so on (col. 11, lines 29-35).

Chenchik et al do expressly teach wherein the mRNA possessing the cap structure is contained in a cell extract. However, methods of isolating mRNA from cells, tissues, organs and microorganisms are well known in the art.

Chenchik '829 teaches a method similar to that of Chenchik et al for synthesizing cDNA. Chenchik '829 further teach steps of isolating RNA from various starting sources such as from eukaryotic cells, single celled organisms such as yeast and multicellular organisms, including plants and animals, different cells from different organism of the same species or cells from different tissue types, such as diseased or normal. Chenchik '829 teaches that the Sample of RNA to be analyzed may be subjected to a number of processing steps known to those of skill in the art (col. 6, lines 39-67). One of ordinary skill in the art at the time of the claimed invention would have a reasonable expectation of success in obtaining mRNA contained in a cell extract for use in a method for synthesizing cDNA possessing a cap structured based on the combined teachings of Chenchik et al in view of Chenchik '829. It would be *prima facie* obvious over the cited references in the absence of secondary considerations.

Regarding claim 12, Chenchik '829 teaches wherein the primer comprises a promoter (col. 8, lines 59-65).

Conclusion

8. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637

01/21/2007